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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/499,526

02/10/2000

Kuanghui Lu

CIBT-P01-058

1398

28120 7590 05/29/2007

FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

DEBERRY, REGINA M

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

05/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/499,526	LU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 87-92, 100, 101, 116-123 and 125-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/07, 6/06</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 13,15-21,23,28-33,39,45,46,50,53,54,57-60,76-78,85,87-94,96-98,100-112,116-123, 125-130.

Continuation of Disposition of Claims: Claims allowed 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 93, 94, 96-98, 102-112 and 130 .

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 July 2006 has been entered.

The Christine Mack Declaration under 37 CFR 1.132 filed 05 June 2006 has been entered.

### ***Status of Application, Amendments and/or Claims***

The amendment filed 31 July 2006 have been entered in full. Claims 1-12, 14, 22, 24-27, 34-38, 40-44, 47-49, 51, 52, 55, 56, 61-75, 79-84, 86, 95, 99, 113-115 and 124 are canceled.

Claims 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-94, 96-98, 100-112, 116-123, 125-130 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

Art Unit: 1647

The information disclosure statement(s)(IDS) filed 05 June 2006 and 12 February 2007 were received and comply with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits.

### ***Withdrawn Objections And/Or Rejections***

The rejection to claims 21, 23, 28, 29, 50, 57-60, 76, 77, 85, 88, 89, 102-112, 116-123, 125-129 under 35 U.S.C. 112, first paragraph, enablement requirement, as set forth at pages 3-4 of the previous Office Action (17 October 2005) is *withdrawn* in view of the amendment (31 July 2006) and the

The rejection to claims 109, 112, 119 under 35 U.S.C. 112, first paragraph, written description (new matter), as set forth at pages 5-6 of the previous Office Action (31 March 2006), is *withdrawn* in view of the amendment (31 July 2006) and the Christine Mack Declaration under 37 CFR 1.132 (05 June 2006) regarding PYY, plasma cholesterol levels and plasma triglyceride levels.

### **Matter of Record**

The allowance of claims 13, 15-20, 30-33, 39, 45, 46, 53, 54, 78, 87, 90-94, 96-98, 100, 101 and 103, as set forth at page 6 of the previous Office Action (31 March 2006), is *withdrawn* in view of the new rejections set forth below.

## **NEW CLAIM REJECTIONS/OBJECTIONS**

### **Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement**

Claims 87-92, 100, 101, 116-123, 125-129 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

**"..comprising an amount of a PYY of SEQ ID NO:2 or a biologically active fragment thereof.." (claims 87-92) OR**

**"..comprising an amount of a PYY(3-36) of SEQ ID NO:3 (claims 122 and 123)**  
does not reasonably provide enablement for:

**"..comprising an amount of a PYY or a biologically active fragment thereof.."**

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are not supported by an enabling disclosure because the specification does not teach how to make any PYY or biologically active fragment of any PYY. The instant claims are drawn to methods that encompass administering any PYY or fragment thereof. The instant specification teaches the homosapien PYY polypeptide sequence as SEQ ID NO:2 (97 amino acids) and the homosapien polynucleotide sequence as SEQ ID NO:1 (582 polynucleotides). The specification teaches SEQ ID NO:3 as the 36 amino acid residue fragment of SEQ ID NO:2 (pages 6, 21 and 22 and Sequence Listing). The specification fails to teach other species of PYY, which the instant claims encompass.

Due to the large quantity of experimentation necessary to generate any species of PYY or biologically active fragment of any species of PYY and screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

#### **Claim Rejections - 35 USC § 112, First Paragraph, Written Description**

Claims 87-92, 100, 101, 116-123, 125-129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification provides adequate written description for PYY polypeptide SEQ ID NO:2 and a biologically active fragment thereof or SEQ ID NO:3. However, the instant claims are drawn to a genus of PYY polypeptides that encompasses virtually every type of PYY species, but are defined only by SEQ ID NO:2 (homosapien PYY). The disclosure fails to provide a representative number of species to describe the genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

Art Unit: 1647

he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. **In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.**

Due to the breadth of the claimed genus and lack of the definitive structural features of the claimed genus, one skilled in the art would not recognize from the disclosure that the Applicant was in possession of the claimed genus. Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:2 and 3, but not the full breadth of the claim (i.e. PYY) meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath*



Art Unit: 1647

makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

**Claim Rejections - 35 USC § 112, Second Paragraph**

Claim 123 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim is indefinite in the recitation of amino acid positions in absence of a referenced SEQ ID NO: The metes and bounds of claim cannot be determined. Amending the instant claim to recite, "...PYY(3-36) of SEQ ID NO:3", would obviate the instant rejection.

***Conclusion***

Claims 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 93, 94, 96-98, 102-112 and 130 are allowed.


Claims 87-92, 100, 101, 116-123, 125-129 are rejected.

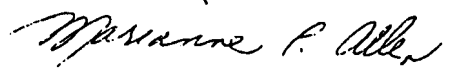
Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
RMD  
5/23/07

  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
5/24/07  
ACU1647